

APPLICANTS: Farmer  
U.S.S.N.: 09/647,695

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims**

1. (previously amended) A method for decreasing serum cholesterol and increasing serum HDL in a patient comprising administering to the digestive tract of said patient an effective amount of a composition comprising a viable lactic acid-producing bacteria and a therapeutic agent comprising an effective amount of a cholesterol-reducing agent and a bifidogenic oligosaccharide, wherein said lactic-acid producing bacteria is *Bacillus coagulans*.
4. (original) The method of claim 1 wherein said lactic acid-producing bacteria is *Bacillus coagulans* subspecies Hammer.
8. (original) The method of claim 1 wherein said composition contains  $10^5$  to  $10^{10}$  viable bacterium per gram of composition.
9. (original) The method of claim 1 wherein said administering comprises oral ingestion of said composition.
10. (original) The method of claim 1 wherein said administering comprises introducing into the digestive tract from 0.1 to 5 grams per day of said composition.
11. (original) The method of claim 1 wherein said administering comprises introducing into the

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digestive tract from  $10^8$  to  $10^{10}$  viable bacterium per day.

12. (previously amended) The method of claim 11 wherein said administering comprises introducing into the digestive tract from  $5 \times 10^8$  to  $5 \times 10^9$  viable bacteria per day.

13. (original) The method of claim 1 wherein said bifidogenic oligosaccharide is selected from the group consisting of fructo-oligosaccharide, gluco-oligosaccharide, and trisaccharide raffinose.

14. (original) The method of claim 13 wherein fructo-oligosaccharide comprises polymers of fructose and glucose having a polymer chain length of from about 4 to 100 sugar units.

15. (original) The method of claim 1 wherein said composition comprises about 10 milligrams to about 1 gram of bifidogenic oligosaccharide per gram of composition.

16. (original) The method of claim 1 wherein said composition comprises from 100 to 500 milligrams of bifidogenic oligosaccharide per gram of composition.

17. (original) The method of claim 1 wherein said administering comprises introducing into the digestive tract from 10 milligrams to 20 grams of bifidogenic oligosaccharide per day.

18. (original) The method of claim 17 wherein said administering comprises introducing into the digestive tract from 150 milligrams to 5 grams of bifidogenic oligosaccharide per day.

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19. (original) The method of claim 1 wherein said cholesterol-reducing agent is selected from the group consisting of a statin, a bile sequestering compound, a fiber product capable of binding cholesterol, niacin and aspirin.

20. (original) The method of claim 19 wherein said statin is selected from the group consisting of cerivastatin, fluvastatin, lovastatin, pravastatin and simvastatin.

21. (original) The method of claim 20 wherein said administering comprises introducing into the digestive tract from 10 to 80 milligrams of statin per day.

22. (original) The method of claim 19 wherein said bile sequestering compound is selected from the group consisting of colestipol and cholestyramine.

23. (original) The method of claim 22 wherein said administering comprises introducing into the digestive tract from 1 to 20 grams of bile sequestering compound per day.

24. (previously amended) The method of claim 19, wherein said fiber product is selected from the group consisting of gemfibrozil, fenofibrate, psyllium, bran, glucomannan and Jerusalem artichoke flour.

25. (original) The method of claim 24 wherein said administering comprises introducing into the

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digestive tract from 500 milligrams to 50 grams of fibrin per day.

26. (original) The method of claim 1 wherein said compost further comprises a cholic acid complexation agent.

27. (previously amended) The method of claim 26 wherein said complexation agent is a salt of a metal selected from the group consisting of calcium, chromium, copper, iodine, iron, magnesium, manganese, potassium sodium, and zinc

28. (original) The method of claim 27 wherein said metal salt is provided in the form of calcium citrate, potassium gluconate, magnesium citrate or chromium picollinate.

29. (original) The method of claim 1 wherein said composition further comprises a food substance, flavoring, vitamin or mineral.

30. (original) The method of claim 1 wherein said patient is at risk for atherosclerosis, arterial sclerosis, myocardial infarction, heart attack, diabetes, coronary heart disease, angina pectoris or unstable angina.

77. (previously amended) A method for decreasing serum cholesterol and increasing serum HDL in a patient comprising administering to the digestive tract of said patient an effective amount of a composition comprising a viable lactic acid-producing bacteria and a therapeutic agent selected

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from the group consisting of an effective amount of a cholesterol-reducing agent and a bifidogenic oligosaccharide, wherein said lactic-acid producing bacteria is *Sporolactobacillus P44*.

78. (newly added) A method for decreasing serum cholesterol and increasing serum HDL in a patient comprising administering to the digestive tract of said patient an effective amount of a composition comprising viable lactic acid-producing *Bacillus coagulans* bacteria.

79. (newly added) A method for decreasing serum cholesterol and increasing serum HDL in a patient comprising administering to the digestive tract of said patient an effective amount of a composition comprising viable lactic acid-producing bacteria consisting essentially of *Bacillus coagulans* bacteria.